IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., *Plaintiffs,* v. JOHNSON & JOHNSON, INC. and CORDIS CORPORATION, *Defendants.*	**PUBLIC VERSION** C.A. No. 07-333-SLR C.A. No. 07-348-SLR C.A. No. 07-409-SLR
BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., *Plaintiffs,* v. JOHNSON & JOHNSON, INC., CORDIS CORPORATION, and WYETH, *Defendants.*	C.A. No. 07-765-SLR

BSC'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF U.S PATENT NOS. 7,217,286, 7,223,286, 7,229,473, AND 7,300,662 UNDER 35 U.S.C. § 112

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INTRODUCTION

Plaintiffs Boston Scientific Corporation and Boston Scientific Scimed, Inc., (collectively, "BSC") respectfully submit this reply brief in support of their Motion for Summary Judgment of Invalidity of U.S Patent Nos. 7,217,286, 7,223,286, 7,229,473, and 7,300,662 under 35 U.S.C. § 112 (D.I. 257) ("Opening Brief"). In its Response Brief in Opposition to Plaintiffs' Motion for Summary Judgment of Invalidity of U.S. Patent Nos. 7,217,286, 7,223,286, 7,229,473, and 7,300,662 under 35 U.S.C. § 112 (D.I. 306) ("Response"), Defendants Johnson & Johnson, Inc. and Cordis Corporation (collectively, "Cordis") do not – and cannot – dispute the following material facts set forth in BSC's Opening Brief:

- The common specification of U.S. Patent Nos. 7,217,286 ("the '7286 patent"), 7,223,286 ("the '3286 patent"), and 7,229,473 ("the '473 patent") (collectively, "the 1997 Patents") fails to disclose any example, figure, diagram, structure, formula, or physical property of any "macrocyclic lactone analog" of rapamycin (D.I. 257 at 6-8)[1];
- **REDACTED**
- The pharmacologic effect of a macrocyclic lactone analog of rapamycin cannot not be predicted (*id.* at 10-13);
- The specification of U.S. Patent No. 7,300,662 ("the '662 patent") also fails to disclose any example, figure, diagram, structure, formula, or physical property of any "macrocyclic triene analog" of rapamycin (*id.* at 24-25);
- **REDACTED**
- The development of drug-eluting stents based on rapamycin analogs was highly unpredictable in 1997-1998, and remained unpredictable in 2001. (*Id.* at 13-14, 27-28.)

[1] Unless otherwise stated, all references to Docket Item numbers are in Civil Action No. 07-333-SLR.

It is this evidence, together with admissions of the inventors (and of other Cordis witnesses) – not "attorney argument," as Cordis contends – on which BSC relies in moving for summary judgment under 35 U.S.C. § 112. The Federal Circuit has found precisely this type of evidence sufficient to support summary judgment for nonenablement. *See Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1000 (Fed. Cir. 2008) (upholding summary judgment of nonenablement based on analysis of specification and expert opinions).

There is no inconsistency in BSC's arguments that the asserted claims are both "obvious" and not enabled. The vast majority of the asserted claims are directed to the use of rapamycin ***or*** a rapamycin analog on a stent. As set forth in BSC's motions for summary judgment of invalidity under 35 U.S.C. § 103, the prior art discloses the use of rapamycin on a stent as claimed in the asserted patents. The prior art also discloses at least one rapamycin analog that could be used on a stent. What is not disclosed in the prior art is the ***full range*** of rapamycin analogs that possibly fall within the asserted claims.

It is black letter law that the full scope of the invention must be enabled for a claim to be valid. **REDACTED** There is no real dispute, however, that the patents fail to teach one of ordinary skill in the art how to make and use (or even to isolate) each compound that could be considered a "macrocyclic lactone analog" or a "macrocyclic triene analog" (even under Cordis's overly narrow definitions of those terms). As result, it cannot be disputed that the full scope of the claims is not enabled.

Cordis's other arguments also lack merit. **REDACTED**

[2]

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[2] **REDACTED**

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See *Sitrick*, 516 F.3d at 1001 ("[Defendant] argues that the testimony of its expert . . . creates a genuine issue of material fact as to the enablement of [the full scope of the claimed invention]. The district court correctly held that [the expert's] opinion regarding enablement did not raise a triable issue of fact because it was: (1) 'conclusory' and 'unsupported by any actual information,' and (2) presented by a person who 'admitted to not being skilled in [the pertinent field] . . .'"). In any event, the overwhelming evidence shows that such efforts would be – and historically have been – prolonged and complex. These difficulties are only compounded in the case of the '662 patent, whose claims require the demonstration of clinical benefits, including specific dosage ranges and "in-stent-late loss" results.

Cordis also relies on the conclusory statements of its experts in an attempt to show that the inventors were in possession of the invention(s) of the asserted claims. If one examines the patents' specifications and the inventors' depositions, however, it becomes clear that there is no evidence that the inventors were in possession of a stent coated with a mixture of a polymer and a macrocyclic lactone or triene analog of rapamycin. In determining whether the inventors were in possession of the claimed invention, the Court should look to the patents and the inventors' testimony – not to the declarations of Cordis's experts.

Finally, Cordis's arguments as to the definiteness of the asserted claims depend entirely on the Court's adoption of Cordis's proposed constructions, which are transparently framed to ensure the claims' validity while still capturing the accused products. Cordis does not attempt to argue the definiteness of the claims under any other construction.

For these reasons, which are explained in more detail below, the Court should grant BSC's Motion for Summary Judgment of Invalidity of U.S Patent Nos. 7,217,286, 7,223,286, 7,229,473, and 7,300,662 under 35 U.S.C. § 112.

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I. CORDIS HAS FAILED TO RAISE A GENUINE ISSUE OF MATERIAL FACT PRECLUDING SUMMARY JUDGMENT THAT THE ASSERTED CLAIMS OF THE 1997 PATENTS ARE INVALID FOR NONENABLEMENT AND LACK OF WRITTEN DESCRIPTION

The 1997 Patents represent no more than a bare idea that, perhaps, rapamycin could be incorporated into a polymer and used therapeutically on a stent. They offer no testing, no data, and no empirical evidence in support of this idea. With respect to "macrocyclic lactone analogs" of rapamycin, their disclosure is even more minimal. Indeed, the sole disclosure in the 1997 Patents of any macrocyclic lactone analogs occurs in their description of "agents" employed in certain experimental embodiments or approaches, including "Rapamycin (sirolimus) structural analogs (macrocyclic lactones) and inhibitors of cell-cycle progression." (D.I. 258, Ex. 9 (BSC-SJA-1961) at 6:4-5.)[3] The patents do not suggest the structure of such analogs, or teach how they can be synthesized, screened, tested, or developed into a therapeutic agent (other than to hint that they should be macrocyclic and contain a lactone group, features common to potentially millions of compounds). Nor do they provide any evidence that the inventors were actually in possession of a macrocyclic lactone analog for use on a stent and as a therapeutic agent after controlled release.

A. There Is No Genuine Issue Of Material Fact As To The Lack Of Enablement Of The 1997 Patents

The enablement provision of Section 112 imposes two requirements. *First*, the ***full scope*** of the invention must be enabled – not merely some examples that might be useful as a starting point for research. *See Sitrick*, 516 F.3d at 999. *Second*, a patent's specification must enable one of skill in the art ***to make and to use*** the invention without undue experimentation – not merely to confirm the existence of an independently created invention. *See LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005). Cordis's Response fails to account for either of these basic requirements.

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[3] Exhibits 1-37, labeled BSC-SJA-1831 to BSC-SJA-2228, are attached to BSC's Appendix In Support of its Motion for Invalidity under 35 U.S.C. §112 (D.I. 258). Exhibits 38-41, labeled BSC-SJA-2323 to BSC-SJA-2350, are attached to BSC's Supplemental Appendix in Support of its Motion for Invalidity.

1. The 1997 Patents Fail To Teach One How To Make Or Use The Full Scope Of The Invention

As established in BSC's Opening Brief, there are at least tens of thousands of possible macrocyclic lactone analogs of rapamycin (also known as sirolimus). (D.I. 257 at 10.) It is undisputed that the 1997 Patents do not disclose or describe a single one. Cordis claims, however, that in 1997 "a person of ordinary skill in the art would have been aware of at least twenty-five sirolimus analogs which had the exact same lactone ring as the parent compound." (D.I. 306 at 11.) Based on the fact that these analogs were "publicly known," Cordis suggests it would have been a "routine" matter to identify and develop them as therapeutic agents for use on stents. (*Id.* at 11, 12.)

Cordis's reliance on these 25 rapamycin analogs allegedly known to the public misses the mark. The Federal Circuit has instructed that *"[t]he **full scope*** of the claimed invention must be enabled." *Sitrick*, 516 F.3d at 999 (emphasis added). The *Sitrick* court explained the "rationale for this statutory requirement":

> Enabling the full scope of each claim is 'part of the quid pro quo of the patent bargain.' A patentee who chooses broad claim language must make sure the broad claims are fully enabled. 'The scope of the claims must be less than or equal to the scope of the enablement' to 'ensure[ ] that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.

Id. Here, Cordis could have limited its claims to rapamycin or even to the 25 analogs allegedly known to the public in 1997, but chose not to do so. It chose instead to draft its claims so broadly as to cover ***any*** macrocyclic lactone analog. Indeed, Cordis and its experts in this litigation have taken the position that the claims of the 1997 Patents cover ***all*** macrocyclic lactone analogs of rapamycin – even those that were unknown in April 1997. (*Supplemental Appendix in Support of BSC's Motion for Summary Judgment of Invalidity under 35 U.S.C. § 112*, Ex. 38 (BSC-SJA-2325) at 117:8-13.) Thus, even if some of the 25 known examples of rapamycin analogs were actually suitable to function as a therapeutic agent when released from a stent, the full scope of the claims would still not be enabled. *See In re Vaeck*, 947 F.2d 488, 496

(Fed. Cir. 1991) ("Where . . . a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure for an invention involving a 'predictable' factor such as a mechanical or electrical element."). Because Cordis does not even attempt to show that any of the many other known and unknown macrocyclic lactone analogs are enabled by the teachings of the 1997 Patents (or by what was known in 1997), the asserted claims must be held to be invalid as not enabled as a matter of law. *See Sitrick*, 516 F.3d at 999-1000.[4]

2. Cordis Applies Too Low A Standard Of Enablement

Even if Cordis were entitled to disregard the full scope of the claimed invention (which it is not), its position would still be flawed because it is based on an inappropriately low standard of enablement. **REDACTED**

[4] Cordis's reliance on these 25 examples of rapamycin analogs, which are not disclosed in the patent, is itself improper. The Federal Circuit has made clear that "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1283 (Fed. Cir. 2007) (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997)). There can be no dispute that one of the allegedly novel features of the asserted claims of the 1997 Patents is a drug-coated stent based on a "macrocyclic lactone analog" of rapamycin. In fact, as discussed in BSC's Opening Brief, Cordis specifically created these new claims following the successful clinical results of Abbott's and BSC's everolimus-eluting stents. (D.I. 257 at 5-6.) In its request to seek expedited examination of the 1997 Patents, Cordis stated that the asserted claims are "directed to a device comprising a metallic stent, a biocompatible polymeric carrier and a drug. The drug is a rapamycin or a macrocyclic lactone analog thereof." (D.I. 258, Ex. 4 at BSC-SJA-1886.)

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By failing to require that the specification enable a skilled artisan to make and use the claimed invention, Cordis and Dr. Sabatini misstate the enablement standard. *See LizardTech.*, 424 F.3d at 1345 (the specification must "enable a person of skill in the art to make and use the full scope of the invention without undue experimentation"). Here, making macrocyclic lactone analogs is in and of itself arduous and challenging. (D.I. 257 at 10.) And, identifying a chemical compound for use as a therapeutic drug on a stent is not at all a predictable endeavor. (*Id.* at 11-14.)

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In such a context, a patentee cannot rely on broad descriptions of a "genus" of chemical compounds. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1214 (Fed. Cir. 1991) ("Considering the structural complexity of the EPO gene, the manifold possibilities for change in its structure, with attendant uncertainty as to what utility will be possessed by these analogs, we consider that more is needed concerning identifying the various analogs that are within the scope of the claim, methods for making them, and structural requirements for producing compounds with EPO-like activity."). As the Supreme Court itself has stated, "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner v. Manson*, 383 U.S. 519, 536 (1966).

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3. Even Applying Cordis's Enablement Standard, Undue Experimentation Is Required To Make And Use The Invention Of The 1997 Patents

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Even if potential macrocyclic lactone analogs of rapamycin were to be identified and obtained, a person skilled in the art must (1) conduct extensive *in vitro* screening; (2) perform animal studies; and (3) conduct human clinical trials. (D.I. 257 at 10-14.) Moreover, in 1997-98, this work would necessarily have been undertaken in a climate of great uncertainty. The specification itself admits that (1) "[t]o date, the ideal coating material has not been developed;" (2) "attainment of a therapeutically effective dose may not be possible;" and (3) clinical results "have shown conflicting or negative results so that no pharmacological agents are as yet clinically available to prevent post-angioplasty restenosis." (D.I. 258, Ex. 9 (A1960) at 3:59-60, 4:35-40, 4:45-48.)[6]

Moreover, the tests one would need to perform are by no means rote. Cordis mentions FKBP12 and TOR ("target of rapamycin") binding assays (*see* D.I. 306 at 8-9, 11, 32), but

[6] Cordis's citation of the Hårdhammar article on pig studies of a heparin coated stent for the proposition that a person skilled in the art could have followed the protocol in that article to test a stent coated with a macrocyclic lactone analog (D.I. 306 at 12) is unavailing. *First*, heparin is a polysaccharide (polymer consisting of sugars) (*see* Ex. 41 at BSC-SJA-2350) and has no structural relationship to rapamycin. Thus, the biological activities, pharmacological effects, and toxicological profile of heparin are unrelated to those of rapamycin analogs. *Second*, the authors actually observe that their protocol did not result in the reduction of smooth muscle cell proliferation; in fact, it caused an increase in proliferation. (D.I. 312 at A1626.)

FKBP12 and TOR are not even mentioned in the 1997 Patents. Thus, there is no support for the notion that one would have gleaned from those patents that these binding assays are appropriate tests to identify a macrocyclic analog of rapamycin. In any case, these are but two of the many possible *in vitro* screening tests that one skilled in the art might conduct to select analog candidates for further evaluation. Neither was used in Wyeth's arduous attempts to identify potential rapamycin analogs for therapeutic use. **REDACTED**

Moreover, such *in vitro* tests do not establish a compound's pharmacological efficacy as a stent coating material for human therapeutic use. In particular, whether a compound binds to another compound in a test tube gives little indication as to whether it will be suitable for use in a stent coating or whether it will be effective therapeutically in an animal or a human. (*See* D.I. 257 at 10-14.) Rather, to make this determination, one must undertake animal and human trials (*see id.* at 19), which would hardly constitute "routine experimentation." Under the case law cited in BSC's Opening Brief, any efforts requiring this amount of experimentation are proof positive of nonenablement.[8] Against this evidence, Cordis's conclusory expert declarations

[7] **REDACTED**

[8] With respect to the 1997 Patents, Cordis fails to distinguish any authority cited in BSC's Opening Brief, much less the controlling authority in *Auto. Techs.*, where the Federal Circuit affirmed the district court's holding of summary judgment of nonenablement under circumstances less compelling than here. (*See* D.I. 257 at 14-18; D.I. 306 at 31-32.) Cordis also fails to address meaningfully any of the *Wands* factors, each of which, as detailed in BSC's Opening Brief, supports a finding of nonenablement. (*See* D.I. 257 at 18-21; D.I. 306 at 33.)

attesting to the "routine" nature of the work should be disregarded, and summary judgment of nonenablement should be entered. *See Sitrick,* 516 F.3d at 1001 ("Conclusory expert assertions cannot raise triable issues of material fact on summary judgment."); *Genentech*, 108 F.3d at 1367 ("[A]n expert's opinion on the ultimate legal issue [of enablement] must be supported by something more than a conclusory statement.") (citation omitted).

B. No Genuine Issue Of Material Fact Exists As To Lack Of Written Description

In addition to the lack of enabling disclosure, it is entirely beyond dispute that the inventors themselves did not have possession of the full scope of the claimed invention as it pertained to macrocyclic lactone analogs. As a consequence, the patents' specification fails to describe such analogs at all. This deficiency in patent disclosure should not be surprising; the inventors testified that their efforts were completely focused on developing rapamycin for use on a stent. **REDACTED**

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The premise that the patents show the inventors to have been in possession of analogs identified and defined by that mechanism is unsupportable.

In any case, when patent claims broadly encompass the use of a class of chemical compounds, as the claims do here, the written description must allow one skilled in the art to identify or describe the members of the class. *Regents of Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997); *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927 (Fed. Cir. 2004). It is not enough to define the class member by what it does or how it might be discovered. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002). Functional descriptions must be "coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Rochester*, 358 F.3d at 925 (citing *Enzo*, 323 F.3d at 964).

Cordis fails to show such a correlation here. While Cordis argues that the specification provides "considerable information on the properties that the drug must have, including a particular effect on cell-cycle progression" (D.I. 306 at 33), the passages cited by Cordis actually: (1) refer to rapamycin, not a macrocyclic lactone analog thereof; and (2) only describe rapamycin's biological activities *in vitro*. (D.I. 258, Ex. 9 (BSC-SJA-1961) at 5:38-39; 5:44-51.) Moreover, none of the evidence cited by Cordis specifies how the structure of a macrocyclic lactone analog correlates to any functions required by the patent claims (such as, in claim 1 of the '7286 patent, inhibiting neointimal proliferation) – let alone how such a correlation would have been known in 1997, and known to be applicable to any "macrocyclic lactone analog."

In sum, there may be close cases where summary judgment of invalidity under 35 U.S.C. § 112's written description requirement would be inappropriate, but this is not one of them. The undisputed evidence shows that the inventors of the 1997 Patents: (1) did not know how to synthesize or isolate any macrocyclic lactone analogs; (2) were unaware of the existence of any macrocyclic lactone analogs; and (3) never worked toward the use of macrocyclic lactone

analogs in their invention. For Cordis now to claim that the inventors were in possession of such "macrocyclic lactone analogs" flaunts the very purpose of the written description requirement. As the Federal Circuit has cautioned (quoting the Supreme Court), "nothing can be more just and fair, both to the patentee and the public, than that the former should understand, and correctly describe, just what he has invented, and for what he claims a patent." *LizardTech,* 424 F.3d at 1346 (quoting *Merrill v. Yeomans*, 94 U.S. 568, 573-74 (1876)). For these reasons, the Court should enter summary judgment that the asserted claims are invalid as a matter of law for failure to satisfy the written description requirement.[9]

II. CORDIS HAS FAILED TO RAISE A GENUINE ISSUE OF MATERIAL FACT PRECLUDING SUMMARY JUDGMENT THAT THE ASSERTED CLAIMS OF THE '662 PATENT ARE INVALID FOR NONENABLEMENT AND LACK OF WRITTEN DESCRIPTION

A. The Asserted Claims Of The '662 Patent Are Not Enabled

For the same reasons that BSC is entitled to summary judgment of nonenablement of the asserted claims of the 1997 Patents, it is also entitled to summary judgment of nonenablement of the asserted claims of the '662 patent. *First*, Cordis has made no effort to show that the full scope of the claimed invention has been enabled, focusing instead on the public disclosure of examples of macrocyclic triene analogs. *Second*, Cordis again applies an unduly low standard for enablement. *Third*, Cordis relies on conclusory allegations that the experimentation required to identify and develop macrocyclic triene analogs for use on a stent would be minimal. This last deficiency is even more grievous in the case of the '662 patent, which claims certain clinical results that Cordis itself has claimed were non-obvious and surprising to those of skill in the art in 2001.

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[9] While the Federal Circuit *en banc* is currently considering whether the written description requirement represents a separate requirement under 35 U.S.C. § 112(1), Cordis does not dispute that under existing law, section 112(1) imposes a distinct disclosure requirement. (*See* D.I. 306 at 33.)

1. There Is No Dispute That The Full Scope Of Invention Of The '662 Patent Is Not Enabled

Cordis attempts to show (as it attempted in the 1997 Patents) that the claims of the '662 patent are enabled by pointing to rapamycin analogs that were known in 2001 (the effective filing date of the '662 patent), but which were not disclosed in the patent's specification.[10] Cordis did not, however, restrict its claims to known rapamycin analogs. Rather, each asserted claim of the '662 patent is directed to the use of rapamycin or ***any*** of its macrocyclic triene analogs on a stent as a drug in a human. Having obtained such broad exclusory scope, Cordis must live up to its end of the bargain by enabling a person skilled in the art to make and use ***the full scope*** of the claimed invention without undue experimentation. Cordis cannot do so and, indeed, does not even attempt to do so. Thus, for the reasons set forth above, the asserted claims of the '662 patent should be found to be not enabled, and invalid, as a matter of law.

2. Dr. Sabatini's Conclusory Assertion Regarding Enablement Is Insufficient

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[10] As in the case of the 1997 Patents (and as discussed in BSC's Opening Brief), Cordis specifically crafted "macrocyclic triene analog" claims in the '662 patent and relied on its alleged novelty in seeking expedited Patent Office review. (D.I. 257 at 24-25.) As a consequence, Cordis should not be permitted to rely on knowledge in the art to teach one how to make and use a drug-coated stent based on a macrocyclic triene analog of rapamycin. *Auto. Techs.*, 501 F.3d at 1283 ("It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.").

Not only do Cordis and Dr. Sabatini apply an unduly low enablement standard (*see supra* section I.A.2), they also overlook the fact that the claims of the '662 patent require that the macrocyclic triene analog, when used as a drug on a stent, deliver specific clinical results. For instance, independent claims 1, 9 and 13 require that the stent "provide[] an in-stent late loss in diameter at about 12 months following implantation in a human of less than about 0.5 mm." (D.I. 258, Ex. 33 at BSC-SJA-2208.) Other claims, such as dependent claims 3, 4, 7 8, 11, 12, 15, and 16, require defined percentages measuring "in-stent diameter stenosis." (*Id.*) Cordis itself has insisted that "the claimed clinical results are important parts of the claims and cannot simply be disregarded." (D.I. 313 in Case No. 07-765-SLR, at 17.) As noted in BSC's Opening Brief, other claims of the '662 patent require specific dosage ranges for the "macrocyclic triene analog." (D.I. 257 at 26-27.) For example, claims 1 and 9 of the '662 patent are directed to a stent (or the use of a stent) coated with a biocompatible polymer having the claimed amount (64 μg to about 197 μg) of rapamycin or a macrocyclic triene analog thereof. (*Id.* at 26.)

Cordis has emphasized the purported effort involved in arriving at these ranges and results:

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Yet nowhere do Cordis or Dr. Sabatini explain how one of skill in the art would know, based on the '662 patent or upon publicly available information, that the same dosage ranges would be

applicable to a given macrocyclic triene analog. Nor do they explain how one of skill in the art could know, based on the '662 patent or publicly known information, that a given macrocyclic triene analog would achieve the claimed clinical results in terms of "in-stent late loss" and "in-stent diameter stenosis." In light of these omissions, there simply can be no question that the claims of the '662 patent are not enabled.

3. Undue Experimentation Is Required To Make And Use The Invention Of The '662 Patent

Finally, as discussed above and in BSC's Opening Brief, knowledge of the existence of a rapamycin analog and performance of *in vitro* binding assays are just the first steps in a long and unpredictable process of developing drug-eluting stents for human use. (*See* D.I. 257 at 9-14, 26-29.) *In vitro* screenings, animal studies, and human trials must subsequently be conducted in order to make and use a drug-eluting stent with a macrocyclic triene analog for human use. (*Id.*) Each of these steps is accompanied by challenges and uncertainties. (*Id.*) There were no established technologies in 2001 to guide a person skilled in the art in such endeavors.[11]

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Not only does this apply the wrong standard for determining enablement, it also represents an assertion unsupported by anything more than Dr. Sabatini's blank avowal. As such, it should be discounted, and summary judgment of

[11] Without any explanation, Cordis again relies on the Hårdhammar article on pig studies of a heparin coated stent. (D.I. 306 at 10.) As discussed above, heparin has a completely different structure and function than rapamycin analogs. Moreover, the Hårdhammar article concluded that its protocol caused an increase in smooth muscle cell proliferation (D.I. 312 at A1626) – the opposite of what is desired in the claimed invention. In addition, although Cordis states that "[t]he specification recommends that one employ in humans "the same dose range as studied in animal models…" (D.I. 306 at 10), the quoted language is directed to rapamycin – not a macrocyclic triene analog thereof. In fact, the specification of the '662 patent teaches that the clinical "benefit in humans is not predictable from animal data." (D.I. 258, Ex. 33 (BSC-SJA-2205) at 11:34-38.) Thus, the Hårdhammar article and the '662 patent offer no practical guidance to begin studying drug-eluting stents based on a macrocyclic triene analog of rapamycin.

nonenablement should be entered. *See Sitrick*, 516 F.3d at 1001 ("Conclusory expert assertions cannot raise triable issues of material fact on summary judgment."); *Genentech*, 108 F.3d at 1367 ("[A]n expert's opinion on the ultimate legal issue [of enablement] must be supported by something more than a conclusory statement.") (citation omitted).

B. There Is No Genuine Issue Of Material Fact As To Lack Of Written Description

As in the case of the 1997 Patents, the specification of the '662 patent does not disclose any actual drug-eluting stent coated with a macrocyclic triene analog of rapamycin that is suitable for human use. (*See* D.I. 257 at 30-31.) Thus, for the same reasons set forth above in connection with the 1997 Patents, and as explained in BSC's Opening Brief, the '662 patent should be held to be invalid for failing to satisfy the written description requirement of 35 U.S.C. § 112. (*See id.* at 30-31.)[12]

III. THE ASSERTED CLAIMS ARE INDEFINITE

Contrary to Cordis's assertions, the issue of the claims' indefiniteness (like the issue of the claims' proper construction) is a legal one – one amenable to resolution prior to trial. *See Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001) (whether a claim is invalid for indefiniteness is a legal conclusion drawn from the court's performance of its duty as the construer of patent claims).[13] For the reasons set forth below, the Court can and should find that the asserted claims are indefinite and thus invalid.

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[12] Cordis's reliance on *Enzo* (cited in D.I. 306 at 23-24), is misplaced. In *Enzo*, the court considered whether a reference in the specification to deposits of nucleotide sequences in a public depository could satisfy the written description requirement of claimed DNA sequences where a person of skill in the art reading the accession numbers disclosed in the specification could obtain the claimed sequences from the depository. 323 F.3d at 962-67. There are no public depositories for macrocyclic triene analogs of rapamycin, and Cordis has not disclosed any accession numbers in the specification to allow someone to retrieve a macrocyclic triene analog.

[13] In *BJ Servs. Co. v. Halliburton Energy Servs., Inc.* (on which Cordis relies for the proposition that the court should wait until the jury trial to decide the definiteness issue, *see* D.I. 306 at 29), the court indicated that indefiniteness issues may be suitable to resolution by a jury "where the issues are factual in nature." 338 F.3d 1368, 1371-72 (Fed. Cir. 2003). Here, the

In its Opening Brief, BSC described the overbreadth and ambiguity of the terms "macrocyclic lactone analog" and "macrocyclic triene analog." **REDACTED**

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Cordis's argument as to the definiteness of the asserted claims rises and falls with its proposed constructions of "macrocyclic lactone analog" and "macrocyclic triene analog." Under those constructions, the elements are defined narrowly to mean that a covered molecule must possess precisely the same macrocyclic ring as rapamycin and perform precisely the same functions as those ascribed by Cordis to rapamycin (binding with FKBP12 and TOR, and inhibition of smooth-cell proliferation).[15]

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indefiniteness issues turn on whether the Court chooses to narrow the rapamycin analog claim terms based on Cordis's proposed constructions, which is a legal issue.

[14] In contrast, in *Exxon Research and Eng'g Co. v. United States* (on which Cordis relies in its Response (D.I. 306) at pages 26 and 28), the specification supplied an objective, numerical boundary for delineating the scope of the disputed claim term. 26 F.3d 1371, 1377 (Fed. Cir. 2001).

[15] As explained in BSC's *Markman* Brief, Cordis's attempts to narrow "macrocyclic lactone analog" and "macrocyclic triene analog" in this fashion are improper. The intrinsic evidence shows that the patentee knew how to narrow a rapamycin analog through functional language when he wanted to do so. Indeed, claim 1 of the '662 patent explicitly recites an analog "that

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Even more troubling is the fact that Cordis's construction (as set forth in detail in BSC's claim construction papers) is utterly arbitrary, having been designed to capture everolimus while avoiding other rapamycin analogs known in the prior art. The deposition testimony of Cordis's witnesses shows that the distinctions it has drawn are meaningless. **REDACTED**

REDACTED

binds FKBP12." (D.I. 258, Ex. 33 (BSC-SJA-2208) at 17:27.) In the vast majority of instances, however, Cordis chose not to impose such a limitation and it never chose to impose a limitation that the analog bind TOR. Cordis's insistence that a rapamycin analog must bind TOR is even more unfounded when one considers the '662 patent's statement that "Rapamycin used in this context includes rapamycin and all analogs, derivatives and congeners that bind FKBP12 and possess the same pharmacologic properties as rapamycin." (D.I. 258, Ex. 33 (BSC-SJA-2203) at 7:29-32.) Any statement that the "analogs, derivatives and congeners" should also bind TOR is notably absent.

The position of Cordis and its experts has the bizarre result of forcing the conclusion that known rapamycin analogs are not "macrocyclic lactone analogs" or "macrocyclic triene analogs" for purposes of the asserted patents. **REDACTED**

REDACTED

Such constructions, which (for tactical reasons) cover some analogs of rapamycin but not others, are untenable and, therefore, cannot cure the claims' indefiniteness. The case law is clear that a patentee cannot render an indefinite claim definite by asserting a claim construction that is otherwise not in accord with the intrinsic evidence. *See Datamize LLC v. Plumtree Software, Inc.*, 417 F.3d 1342 (Fed. Cir. 2005) (patent claims held to be indefinite, despite patentee's proffered limiting construction, because the construction was not supported by intrinsic or extrinsic evidence). For these reasons, and for the reasons set forth in BSC's Opening Brief, the asserted claims should be found indefinite.

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16 **REDACTED**

17 **REDACTED**

CONCLUSION

For the foregoing reasons, the Court should grant the motion for summary judgment of invalidity for failure to meet the enablement, written description, and definiteness requirements under 35 U.S.C. § 112.

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